REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below.

Claims 1-11 are pending in this application. Applicants elected Group A, drawn to claims 1-3 and 9-11, directed to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two polypeptide molecular markers in a cell, wherein the markers are selected from at least one of tumor suppressor genes and apoptosis genes, and Group B, claims 1-3 and 9-11, directed to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two molecular markers in a cell, wherein the markers are selected from at least one of her2/neu and p53 (Response to Restriction mailed April 5, 2005). In a subsequent conversation with Examiner Ungar, Applicants acknowledge that claim 2 was withdrawn from the restriction groups.

The Examiner has withdrawn claims 2 and 6-8 from further consideration as being drawn to non-elected inventions (Office Action mailed June 23, 2005, page 2). Claims 9-11 have been cancelled.

Claims 1 and 4 have been amended. Support for the amended claims may be found, for example, on pages 10-18 of the specification. These claim amendments are made to clarify the subject matter therein. Therefore, these amendments are submitted in order to place the claims in condition for allowance, and do not disclaim any subject matter to which the Applicants are entitled.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1, 3-5, and 9-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention (Office Action mailed June 23, 2005, pages 3-4). Applicants respectfully traverse this rejection.

Claims 9-11 have been cancelled; thus, Applicants respectfully requested withdrawal of the rejection of these claims.

The Examiner rejected claims 1, 3-5, and 9-11 as indefinite because claim 1 does not contain a positive process step which clearly relates back to the preamble.

Claim 1 has been amended so the claim now recites steps to the method. Support for the amended claims may be found, for example, on pages 10-18 of the specification.

The Examiner rejected claims 1, 3-5, and 9-11 as indefinite because they appear to be missing a critical element. As mentioned above, claim 1 has been amended and as amended, now recites steps of the method.

The Examiner rejected claims 9 and 10 because claim 9 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claims 9 and 10 have been cancelled, thereby obviating the rejection.

The Examiner rejected claims 9 and 10 because claim 9 recites the phrase "signal intensities are combined and summated." Claims 9 and 10 have been cancelled, thereby obviating the rejection.

The Examiner rejected claim 10 as indefinite in the recitation of "the automatic information processing." Claim 10 has been cancelled, thereby obviating the rejection.

The Examiner rejected claim 10 as indefinite in the recitation of "where appropriate." Claim 10 has been cancelled, thereby obviating the rejection.

It is thus submitted that the claims 1 and 3-5 meet the requirements of 35 USC § 112, second paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 3, 5, and 11 under 35 U.S.C. § 103(a) as unpatentable over Pillai, et al., (Cancer Epidemiology, Biomarkers and Prevention, 5:329-335, 1996) in view of U.S. Patent Application Serial No. US 2002/0045591 (Office Action mailed June 23, 2005, pages 5-11). Applicants respectfully traverse.

To properly maintain a rejection under 35 U.S.C. § 103, three conditions must be met. First, the prior art must have suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the prior art must also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in the Applicant's disclosure. Finally, the prior art reference must teach or suggest all the claim limitations. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Claims 9-11 have been cancelled; thus, Applicants respectfully requested withdrawal of the rejection of these claims.

As amended, the claims recite a method for identifying tumour cells and their precursors comprising the steps of contacting a cell or tissue sample with color marked reagents that specifically bind to the molecular markers, simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Pillai, et al., do not teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities. In addition, the deficiencies of Pillai, et al., are not remedied by US 2002/0045591. That is, US

2002/0045591, also does not teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Since the combination of references does not teach every element of the claimed invention, these references cannot be combined to support a rejection of the claims under U.S.C. § 103(a). MPEP § 2143.

It is therefore submitted respectfully that Pillai, et al., either singly or in combination with US 2002/0045591 fail to teach or suggest the method as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the present rejection.

The Examiner rejected claims 1 and 3-5 under 35 U.S.C. § 103(a) as unpatentable over Pillai, et al., US 2002/0045591, and further in view of Kihana, et al., (Cancer 73:148-153, 1994).

As stated above, neither Pillai, et al., nor US 2002/0045591 teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Kihana, et al., also do not teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

It is therefore respectfully submitted that Pillai, et al., US 2002/0045591, and Kihana, et al., fail to teach or suggest the method as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the present rejection.

The Examiner rejected claims 1 and 9-10 under 35 U.S.C. § 103(a) as unpatentable over Pillai, et al., US 2002/0045591, and further in view of Levenson, et al., (ISAC XX Purdue Cytometry CD ROM Series, May 2000, Vol. 5, Abstract No. 8047) and Stoler (Mod. Pathol. 13:275-284, 2000).

Claims 9 and 10 have been cancelled; thus, obviating the rejection. Applicants respectfully requested withdrawal of the rejection of these claims.

As stated above, neither Pillai, et al., nor US 2002/0045591 teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

Neither Levenson, et al., nor Stoler teach or suggest the steps of simultaneously detecting signal intensities of color mixtures resulting from the markers, and combining and accrediting the signal intensities.

It is therefore respectfully submitted that Pillai, et al., US 2002/0045591, Levenson, et al., and Stoler fail to teach or suggest the method as presently claimed, and that the current invention is novel and

nonobvious in view of the prior art references. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claim Objections

The Examiner objected to claim 4 because it appears that there is an inadvertent typographical error in the claims (Office Action mailed June 23, 2005, page 3).

Applicants submitted a Preliminary Amendment at the time of filing (Preliminary Amendment submitted December 17, 2001). Claim 4 had been amended so it no longer recited "characterized in that..." However, to clarify the claimed subject matter, claim 4 has been amended to recite the marker combinations.

It is submitted that Applicants have overcome the claim objections, and thus, claim 4 is allowable.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections and objections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Ungar is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

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Amended Claims (Attorney Docket No. LeA 35 010)

1. (Currently amended) A method for detecting tumour cells and their precursors in uterine cervical smears by simultaneously detecting at least two molecular markers in a cell or tissue sample comprising

   contacting the cell or tissue sample with color marked reagents that specifically bind said molecular markers,

   simultaneously detecting signal intensities of color mixtures resulting from markers, and

   combining and accrediting the signal intensities.

2. (Withdrawn) The method according to Claim 1, further characterized in that the markers are selected from the group consisting of: tumour suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes.

3. (Previously presented) The method according to Claim 1, characterized in that at least one of the markers comprises her2/neu, p16, p53, MN, mdm-2, bcl-2, EGF receptor, and specific DNA from the HPV subtypes 6, 11, 16, 18, 30, 31, 33, 35, 45, 51 and 52.

4. (Currently amended) The method according to Claim 1, wherein the marker combinations comprise her2/neu ~~with~~ and p16, ~~or~~ EGF-R ~~with~~ and p16, ~~or~~ p53 ~~with~~ and her2/neu, ~~or~~ her2/neu ~~with~~ and mdm-2, ~~or~~ bcl-2 ~~with~~ and p16, ~~or~~ bcl-2 ~~with~~ and her2/neu, or p16 ~~with~~ and p53.

5. (Previously presented) The method according to claim 1, further characterized in that 3 markers are detected.

6. (Withdrawn) A kit for implementing the method according to Claim 1.

7. (Withdrawn) The kit according to Claim 6, further characterized in that the reagents are antibodies or nucleic acids.

8. (Withdrawn) The kit according to Claim 7, characterized in that the antibodies or nucleic acid probes are read directly or indirectly using fluorescent or chromogenic dye substances.

9. (Cancelled).

10. (Cancelled).

11. (Cancelled).